IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF HAWAI'I

BRIAN EVANS, Plaintiff, vs. GILEAD SCIENCES, INC., Defendant.	Case No. 20-cv-00123-DKW-KJM **ORDER (1) GRANTING DEFENDANT'S MOTION TO DISMISS; AND (2) DISMISSING THE FIRST AMENDED COMPLAINT WITH LEAVE TO AMEND**

This product liability case involves *pro se* Plaintiff Brian Evans' use of Truvada®, an FDA-approved prescription drug designed and manufactured by Defendant Gilead Sciences, Inc., for the prevention and treatment of HIV. Gilead has moved to dismiss the complaint for failure to state a claim, Dkt. No. 20, arguing that the claims are preempted by the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, and that Evans has failed to adequately allege facts to support the elements of his claims for failure-to-warn, fraud, and breach of express and implied warranty.

First, Evans' design defect claims are preempted under the FDCA because it was impossible for Gilead to comply with both Hawaii tort law and the FDCA's design approval requirements. Federal regulations, however, permitted Gilead to unilaterally change its Truvada labeling and, thus, Evans' failure-to-warn claims are not preempted. Second, Evans has failed to sufficiently allege that the inadequacy

of the Truvada labeling proximately caused his injuries. Third, Evans has not pled his fraud claim with "particularity" as required by Federal Rule of Civil Procedure 9(b). Lastly, Evans' warranty claims are dismissed as vague and conclusory. Accordingly, Gilead's motion to dismiss Evans' first amended complaint, Dkt. No. 20, is GRANTED. Evans is granted leave to amend all but his federally preempted design defect claims.

FACTUAL & PROCEDURAL BACKGROUND

The following facts are drawn from the allegations in the first amended complaint, "documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007).

A. Truvada® for PrEP

At all times relevant, Defendant Gilead Sciences, Inc. (Gilead) manufactured and marketed the brand-name prescription drug Truvada. *See* Dkt. No. 8 at 1, 3.[1] Truvada contains two active ingredients, one of which is relevant here: Tenofovir disoproxil fumarate (TDF). *Id.* at 4.[2] TDF was approved by the Food and Drug

[1]*See* FDA, *Truvada*, Drugs@FDA: FDA Approved Drugs, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=021752 (last visited August 28, 2020). Because a court may take judicial notice of any undisputed facts in "records and reports of administrative bodies" in ruling on a Rule 12(b)(6) motion to dismiss, *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 999, 1001 (9th Cir. 2018) (quoting *United States v. Ritchie*, 342 F.3d 903, 907–09 (9th Cir. 2003)), the Court will consider relevant records and reports issued by the Food and Drug Administration, including the FDA-approved Truvada labeling.

[2]*See* U.S. Food & Drug Admin. (FDA), Truvada for PrEP Fact Sheet: Ensuring Safe and Proper

Administration (FDA) in October 2001. Dkt. No. 8 at 4.

On August 2, 2004, the FDA approved Truvada for the treatment of HIV infection in adults.[3] On July 16, 2012, the FDA approved Truvada for use by HIV-negative adults as a Pre-Exposure Prophylaxis (PrEP) taken daily to reduce the risk of becoming infected with HIV.[4]

B. Alleged Risks Associated With TDF in Truvada

Plaintiff Brian Evans was prescribed Truvada in October 2018. Dkt. No. 8 at 4. Evans alleges that as a result of taking Truvada, he "has now suffered irreversible damages to his bones." *Id*. at 5. Evans also alleges that he now suffers from, and has been diagnosed with, diffuse arthralgia (*i.e.*, joint pain) and is unable to work. *Id*. at 2, 7.[5]

Evans asserts that, as early as 1997, studies had associated TDF with bone and kidney damage. *See* Dkt. No. 8 at 7–8. In one study, patients who had taken Truvada demonstrated accelerated losses of bone density, resulting in "Osteoporosis [and]

Use 1 (2012) [hereinafter "Truvada Fact Sheet"], https://www.fda.gov/media/83586/download (last visited August 14, 2020); *see also* FDA, *Truvada*, Drugs@FDA: FDA Approved Drugs, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=021752.

[3]U.S. Food & Drug Admin., Drug Approval Package: Truvada (August 2, 2004), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/021752s000_TruvadaTOC.cfm (last visited (August 14, 2004); Letter from Dep't of Health & Human Services to Gilead Sciences, Inc., https://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/021752s000_Truvada_Approv.pdf.

[4]*See* Truvada Fact Sheet, *supra* note 2, at 1.

[5]Evans attaches a letter from his treating physician, stating in part, that Evans did not have "multi-joint pain prior to taking the medication." Dkt. No. 8-1.

other joint and bone conditions." *Id*. at 2–3. By 2001, Gilead allegedly knew that Truvada had to be taken by consumers in high doses to be effective, and thus, patients taking Truvada were at a higher risk for bone and kidney damage. *Id*. at 2, 4, 7.

The Truvada labeling in effect at the time Evans was prescribed Truvada (October 2018) was approved by the FDA on May 15, 2018. Dkt. No. 20-2.[6] The FDA-approved patient labeling states, in relevant part, "**Bone problems** can happen in some people who take TRUVADA. Bone problems include bone pain, or softening or thinning of bones, which may lead to fractures. Your healthcare provider may need to do tests to check your bones." *Id*. at 37 (emphasis in original).

The Truvada labeling also provides information for physicians prescribing Truvada. On the first page, under "WARNINGS AND PRECAUTIONS," the label notes, *inter alia*, "[d]ecreases in bone mineral density (BMD): Consider assessment of BMD in patients with a history of pathologic fracture or other risk factors for osteoporosis or bone loss." *Id*. at 1. Under "DRUG INTERACTIONS," it provides that "Coadministration of TRUVADA with certain HIV-1 protease inhibitors or certain drugs to treat HCV increases tenofovir concentrations. Monitor for evidence of tenofovir toxicity." *Id*. at 1. In a separate section, entitled "Bone Loss and

[6]Truvada's labeling has been revised on sixteen different occasions since the drug was initially approved. *See* FDA, *Truvada*, Drugs@FDA: FDA Approved Drugs, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=021752.

Mineralization Defects," it states:

> In clinical trials in HIV-1 infected adults and in a clinical trial of HIV-1 uninfected individuals, TDF (a component of TRUVADA) was associated with slightly greater decreases in bone mineral density (BMD)[.]
>
> . . . .
>
> Assessment of BMD should be considered for adult and pediatric patients who have a history of pathologic bone fracture or other risk factors for osteoporosis or bone loss.
>
> . . . .
>
> Cases of osteomalacia associated with proximal renal tubulopathy, manifested as bone pain or pain in extremities and which may contribute to fractures, have been reported in association with TDF use [see Adverse Reactions (6.1)]. Arthralgia and muscle pain or weakness have also been reported in cases of proximal renal tubulopathy. Hypophosphatemia and osteomalacia secondary to proximal renal tubulopathy should be considered in patients at risk of renal dysfunction who present with persistent or worsening bone or muscle symptoms while receiving TDF-containing products [see Warnings and Precautions (5.3)].

Dkt. No. 20-2 at 7–8 (brackets in original); *see also id*. at 8 (noting that "ADVERSE REACTIONS" include "Bone Loss and Mineralization Defects"); *id*. at 12 ("In clinical trials of HIV-1 uninfected individuals, decreases in BMD were observed.").

The "PATIENT COUNSELING INFORMATION" in the label further instructs physicians to "[a]dvise the patient to read the FDA-approved patient labeling (Medication Guide)," *id*. at 32, "[i]nform patients that decreases in bone mineral density have been observed with the use of TDF or TRUVADA," and "[c]onsider bone monitoring in patients and uninfected individuals who have a

history of pathologic bone fracture or at risk for osteopenia [see Warnings and Precautions (5.5)]," *id*. at 33 (brackets in original).

Evans alleges the warnings "partially disclosed material facts" and were "contrary to those [Gilead] gave with respect to the exact same drugs in [Europe]." Dkt. No. 8 at 8.

C. TAF is Allegedly "Safer" Than TDF

In April 2001, scientists published research for a different chemical known as tenofovir alafenamide fumarate (TAF). Dkt. No. 8 at 4. TAF, as compared to TDF, was allegedly shown to be substantially more effective against HIV with far less toxicity. *Id*. at 5. Evans alleges Gilead began clinical trials for TAF but kept the results secret until it announced in October 2004 (shortly after Truvada was first FDA-approved) that Gilead was abandoning its research on TAF. *Id*. According to Evans, Gilead "purposefully withheld" TAF, knowing that it was "safer" than TDF, so that the company could "make more money" by continuing to sell Truvada until the Truvada patents expired and the medication could be purchased from generic prescription drug manufacturers. *See id*. at 5, 7; *id*. at 2. In 2010, Gilead began publishing the results of its earlier studies on TAF. *See id*. at 5. Between November 2015 and February 2018, the FDA approved at least four TAF-containing medications manufactured by Gilead. *See id*. at 5.[7]

[7]The four specific drugs are Genvoya, Odefsey, Descovy, and Biktarvy. FDA, Genvoya

As noted, in October 2018, Evans was prescribed Truvada. *Id*. at 4.[8]

D. Evans' Claims

Although the complaint lacks focus and Evans' claims concerning Truvada are difficult to deconstruct, heeding the obligation to construe his complaint liberally, Evans' theory of liability is twofold. First, Evans alleges Gilead failed to adequately disclose on its prescriber and patient labeling for Truvada that: (a) the drug "could cause damage to the kidneys and to the bones of those who ingest it," including "the problems that [Evans] is now suffering" (*i.e.*, diffuse arthralgia); and (b) doctors should "monitor all TDF patients, on a frequent, specific schedule, for the adverse effects of TDF-associated bone and kidney toxicity." *See id*. at 2, 6–7. Evans also alleges Gilead failed to issue any such "warnings until 2018, despite knowing of these effects since 2001." *Id*. at 6. Second, Evans asserts "Gilead purposefully withheld the TAF design, which it knew was safer than TDF, to make

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Approval Package, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/207561Orig1s000TOC.cfm; FDA, Odefsey Approval Package, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/208351Orig1s000TOC.cfm; FDA, Descovy Approval Package, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/208215Orig1_toc.cfm; FDA, Biktarvy Approval Package, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210251Orig1s000TOC.cfm. The approval dates, history, letters, labels, and reviews for each drug are available on the FDA's website and can be accessed through a search using the drug's name. *See* FDA, Drugs@FDA: FDA-Approved Drugs, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm.

[8]Evans also alleges that he was prescribed Truvada by his "healthcare provider, contrary to their obligation to do so, . . . without any testing or bloodwork"; namely, a "negative HIV antibody test." Dkt. No. 8 at 1, 7. Evans does not allege any facts that would indicate that Gilead was somehow responsible for that decision, and Evans has not named his prescribing physician as a Defendant in this lawsuit.

more money." *Id*. at 7; *see also id*. at 6, ¶ 2. Evans' complaint asserts the following product liability claims sounding in negligence and strict liability: (1) "Strict Products Liability – Failure to Warn"; (2) "Negligence and Gross Negligence – Design Defect and Failure to Warn"; (3) "Fraud"; and (4) "Breach of Express and Implied Warranty." *Id*. at 1, 8.

E. Procedural History

Because Evans filed this lawsuit *pro se*, seeking to proceed *in forma pauperis*, the Court conducted its mandatory, *sua sponte* screening of the complaint pursuant to 28 U.S.C. § 1915(a) and dismissed the complaint with leave to amend for failure to state a claim upon which relief may be granted. Dkt. No. 7 at 6; 28 U.S.C. § 1915(e)(2)(B); *Denton v. Hernandez*, 504 U.S. 25, 32 (1992). Evans filed an amended complaint, Dkt. No. 8, which the Court held "may proceed such that Gilead may be served," but noted that "Gilead . . . may still challenge Evans' claims through any means procedurally permitted by the Federal Rules." Dkt. No. 9 at 5.

Pursuant to Federal Rule of Civil Procedure 12(b)(6), Gilead has moved to dismiss all claims. Dkt. No. 20.

STANDARD OF REVIEW

"Federal Rule of Civil Procedure 8(a)(2) requires only 'a short and plain statement of the claim showing that the pleader is entitled to relief,' in order to 'give the defendant fair notice of what the . . . claim is and the grounds upon which it

rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (ellipsis in original) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). "[T]he pleading standard Rule 8 announces does not require 'detailed factual allegations,'" but it does require that "[t]o survive a motion to dismiss [under Rule 12(b)(6)], a complaint must contain sufficient fact[s] . . . to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 555, 570).

A claim becomes plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. In making this assessment, a court "must accept as true all of the factual allegations contained in the complaint," *Erickson v. Pardus*, 551 U.S. 89, 94 (2007), and draw "any reasonable inferences" in favor of the plaintiff. *Johnson v. Riverside Healthcare Sys.*, 534 F.3d 1116, 1122 (9th Cir. 2008). In other words, a plaintiff's "[f]actual allegations must be enough to raise a right to relief above the speculative level on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Twombly*, 550 U.S. at 555 (internal citations omitted). That said, the plausibility standard "demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation," *Iqbal*, 556 U.S. at 678, and "labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id*. (quoting *Twombly*, 550 U.S. at 555).

A court, therefore, judges the sufficiency of a complaint under a two-pronged approach: (1) disregard all "legal conclusions" and "conclusory statements"; and (2) determine whether the remaining "well-pleaded factual allegations," accepted as true, "plausibly give rise to an entitlement to relief." *Iqbal*, 556 U.S. at 678–81. Dismissal is then warranted "where there is no cognizable legal theory or an absence of sufficient facts alleged to support a cognizable legal theory." *Interpipe Contracting, Inc. v. Becerra*, 898 F.3d 879, 886 (9th Cir. 2018) (quoting *L.A. Lakers, Inc. v. Fed. Ins. Co.*, 869 F.3d 795, 800 (9th Cir. 2017)).

DISCUSSION

Gilead asserts various grounds to dismiss each of Evans' claims. Dkt. No 20-1 at 7–9; Dkt. No. 33 at 2–3. Evans' opposition consists almost solely of allegations copied from an antitrust class action complaint filed against Gilead, Dkt. No. 31,[9] which is irrelevant to Evans' product liability claims and the arguments Gilead raises for dismissal. Notwithstanding Evans' failure to meaningfully respond to Gilead's arguments, that alone is insufficient grounds to conclude that the *complaint* fails to

[9]*See* Complaint at ¶¶ 1–15, *Staley v. Gilead Sciences, Inc.*, No. 3:19-cv-02573 (N.D. Cal. May 14, 2019), ECF No. 1.

state a claim, as Gilead must still satisfy its burden as the movant.[10] Therefore, the Court will address Gilead's arguments in turn.

I. Federal Preemption Under the FDCA

The threshold issue raised by Gilead is federal preemption. Gilead argues that Evans' complaint must be dismissed in its entirety because his claims are "all based on his design defect and failure to warn theories" and these two claims are "preempted by federal law." Dkt. No. 20-1 at 20; Dkt. No. 33 at 3. For the reasons that follow, the Court agrees with respect to Evans' design defect claims only.

A. Applicable Preemption Principles

"A fundamental principle of the Constitution"—namely, the Supremacy Clause—"is that Congress has the power to preempt state law." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000) (citing U.S. CONST. art. VI, cl. 2). "In all pre-emption cases, . . . [courts] start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (citations and internal quotation marks omitted). The U.S. Supreme

[10] *See, e.g.*, *V.V.V. & Sons Edible Oils Ltd. v. Meenakshi Overseas, LLC*, 946 F.3d 542, 547 (9th Cir. 2019) (plaintiff "explicitly did not oppose" dismissal); *Stevenson v. City of Seat Pleasant*, 743 F.3d 411, 416 n.3 (4th Cir. 2014) ("Even though Appellants did not challenge the motions to dismiss, we note that the district court nevertheless has an obligation to review the motions to ensure that dismissal is proper."); *Issa v. Comp USA*, 354 F.3d 1174, 1178 (10th Cir. 2003) (holding that "even if a plaintiff does not file a response to a motion to dismiss . . . the district court must still examine the allegations in the plaintiff's complaint and determine whether the plaintiff has stated a claim").

Court "has sometimes used different labels to describe the different ways in which federal statutes may displace state laws—speaking, for example, of express, field, and conflict preemption." *Va. Uranium, Inc. v. Warren*, 139 S. Ct. 1894, 1901 (2019). Gilead relies solely on conflict preemption. *See* Dkt. No. 20-1 at 23.

Conflict preemption exists in two forms: impossibility preemption and obstacle preemption. *See Crosby*, 530 U.S. at 373; *Valle Del Sol Inc. v. Whiting*, 732 F.3d 1006, 1023 (9th Cir. 2013). Gilead argues "it was impossible for Gilead to comply simultaneously with both a purported state law duty" and the requirements imposed by federal law. *See* Dkt. No. 20-1 at 23–31. As such, the requirements for "impossibility preemption" govern.

"Impossibility pre-emption is a demanding defense." *Wyeth*, 555 U.S. at 573. The party invoking this preemption defense must show that it is "'impossible for [that] private party to comply with both state and federal requirements.'" *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011) (quoting *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995)).[11] "[T]he mere possibility of impossibility [i]s not enough." *PLIVA*, 564 U.S. at 624 n.8 (citations and internal quotation marks omitted); *Wyeth*, 555 U.S. at 571; *Rice v. Norman Williams Co.*, 458 U. S. 654, 659

[11]The party asserting the defense bears the "burden [of] establishing [its] pre-emption defense." *See, e.g.*, *Wyeth*, 555 U.S. at 569; *Lusnak v. Bank of Am., N.A.*, 883 F.3d 1185, 1191 (9th Cir. 2018); *Wolfe v. BNSF Ry. Co.*, 749 F.3d 859, 863 (9th Cir. 2014).

(1982) ("The existence of a hypothetical or potential conflict is insufficient to warrant the pre-emption of the state statute").

Therefore, the defining "question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *PLIVA*, 564 U.S. at 620 (citing *Wyeth*, 555 U.S. at 573); *Bates v. Dow Agrosciences L.L.C.*, 544 U.S. 431, 445 (2005) ("The proper inquiry calls for an examination of the elements of the common-law duty at issue; it does not call for speculation as to whether a jury verdict will prompt the manufacturer to take any particular action." (internal citations omitted)).

B. Hawaii Tort Law and the FDCA

With the above principles in mind, the Court must compare state tort duties with federal labeling and design requirements imposed on brand-name drug manufacturers to determine whether it was "impossible" for Gilead to comply with state and federal law. *See PLIVA*, 564 U.S. at 611. Hawaii law applies in this case.[12] The federal law at issue is the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, and its implementing regulations through which the FDA regulates the approval and labeling of brand-name prescription drugs.

[12]Hawaii law applies based on the choice-of-law rules of the forum state. *Klaxon Co. v. Stentor Elect. Mfg. Co.*, 313 U.S. 487, 496–97 (1941); *Senne v. Kan. City Royals Baseball Corp.*, 934 F.3d 918, 928 (9th Cir. 2019); *see Mikelson v. United Servs. Auto. Ass'n*, 111 P.3d 601, 607 (Haw. 2005). Gilead relies primarily on Hawaii product liability law and thus appears to agree. *See, e.g.*, Dkt. No. 20-1 at 12.

1. Duties Under Hawaii Law

Under Hawaii common law, "where a seller or lessor . . . sells or leases a defective product which is dangerous to the user or consumer, and injury results from its use or consumption, the seller or lessor will be held strictly liable in tort for the injury." *Tabieros v. Clark Equip. Co.*, 944 P.2d 1279, 1310 (Haw. 1997) (quoting *Ontai v. Straub Clinic & Hosp.*, 659 P.2d 734, 739 (Haw. 1983)). "A product may be defective" by virtue of its manufacturing, design, or "insufficient warning." *Id.* at 1296 (citation omitted). "A plaintiff may establish a defect for purposes of either strict liability or negligence under three approaches: (1) the 'consumer expectation' test; (2) the 'risk-utility' test; and (3) the 'latent danger' test." *Acoba v. General Tire, Inc.*, 986 P.2d 288, 304 (Haw. 1999) (quoting *Tabieros*, 944 P.2d at 1310).[13]

[13]To establish a design defect under the "consumer expectation" test, "it is enough that the plaintiff demonstrates that because of its manufacture or design, the product does not meet the reasonable expectations of the ordinary consumer or user as to its safety." *Tabieros*, 944 P.2d at 1311 (quoting *Ontai*, 659 P.2d at 739). Under the "risk-utility test," "a product may alternatively be found defective in design if the plaintiff demonstrates that the product's design proximately caused his injury and the defendant fails to establish, in light of the relevant factors, that, on balance, the benefits of the challenged design outweigh the risk of danger inherent in such design." *Id.* (quoting *Ontai*, 659 P.2d at 739–40); *see id.* at 1310 (noting that relevant factors may include "the gravity of the danger posed by the design, the likelihood that such danger would cause injuries, the mechanical feasibility of a safer alternative design at the time that the product was manufactured, the financial cost of an improved design, and the adverse consequences, if any, to the product and the consumer that would result from an alternative design."). The third theory—the "latent danger" test—provides that "the product is defective in design, even if faultlessly made, if the use of the product in a manner [that] is intended or reasonably foreseeable . . . involves a substantial danger that would not be readily recognized by the ordinary user of the product *and the manufacturer fails to give adequate warnings of the danger*." *Tabieros*, 944 P.2d at 1310 (emphasis in original); *Masaki v. General Motors Corp.*,

2. FDCA Requirements

Federal law, in this case, is more robust than state law. Under the FDCA, drug manufacturers must obtain approval from the FDA before bringing a new drug to market. 21 U.S.C. § 355(a). "It is beyond dispute that the federal statutes and regulations that apply to brand-name drug manufacturers," like Gilead, "are meaningfully different than those that apply to generic drug manufacturers." *PLIVA*, 564 U.S. at 626. "A brand-name manufacturer . . . is responsible for the accuracy and adequacy of its label." *See, e.g.*, *PLIVA*, 564 U.S. at 613 (citing 21 U.S.C. §§ 355(b)(1), (d)). "It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Wyeth*, 555 U.S. at 571 (citations omitted). "A manufacturer seeking generic drug approval, on the other hand, is responsible for ensuring that its warning label is the same as the brand name's." *See, e.g.*, *PLIVA*, 564 U.S. at 613 (citing 21 U.S.C. § 355(j)(2)(A)(v), (j)(4)(G); 21 C.F.R. §§ 314.94(a)(8), 314.127(a)(7)).

"In the case of a new brand-name drug, FDA approval can be secured only by submitting a new-drug application (NDA)." *Bartlett*, 570 U.S. at 476 (noting that the "process of submitting an NDA is both onerous and lengthy"). The FDA may approve the drug "only if it determines that the drug in question is 'safe for use' under 'the conditions of use prescribed, recommended, or suggested in the proposed

780 P.2d 566, 579 (Haw. 1989).

labeling thereof.'" *Id*. (quoting 21 U.S.C. § 355(d)). FDA approval of a new drug also includes approval of the "exact text" on the final label. *Wyeth*, 555 U.S. at 568; 21 C.F.R. § 314.105(b).

After approval, the FDA's "changes being effected" (CBE) regulation permits brand-name drug manufacturers to revise their labels "to reflect newly acquired information" if the change is designed to "add or strengthen a contraindication, warning, precaution, or adverse reaction for which [there is] evidence of a causal association" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product." *See, e.g.*, 21 C.F.R. § 314.70(c)(6)(iii)(A), (C); *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1679 (2019); *PLIVA*, 564 U.S. at 614–15, 624. Brand-name drug manufacturers "may make the labeling change upon filing [a] supplemental application with the FDA; [they] need not wait for FDA approval." *Wyeth*, 555 U.S. at 568 (citing 21 C.F.R. §§ 314.70(c)(6)(iii)(A), (C)); *Albrecht*, 139 S. Ct. at 1673, 1679; *PLIVA*, 564 U.S. at 624 ("They need only simultaneously file a supplemental application with the FDA."). "[T]he FDA retains authority to reject" these unilateral labeling changes made pursuant to the CBE regulation. *Wyeth*, 555 U.S. at 571. But the possibility of rejection does not preempt state law. For a brand-name manufacturer to establish that "it was impossible" to comply with both federal and state labeling requirements, it must produce "clear evidence that the FDA would not

have approved a change to [the] label." *Id.*; *Albrecht*, 139 S. Ct. at 1672 (holding that "this question of pre-emption is one for a judge to decide, not a jury"). "[T]he mere fact that the FDA approved [the brand-name drug]'s label does not establish that it would have prohibited such a change." *Wyeth*, 555 U.S. at 573.

The FDCA is different for generic drug manufacturers. Since Congress passed what is commonly known as the "Hatch-Waxman Act" in 1984, now "a generic drug" may simply be approved if "the generic drug is identical to the already-approved brand-name drug" in terms of active ingredients, route of administration, dosage form, strength, and labeling. *See Bartlett*, 570 U.S. at 477; *PLIVA*, 564 U.S. at 612; 21 U.S.C. §§ 355(j)(2)(A)(ii)–(v), (8)(B). Moreover, unlike brand-name drug manufacturers, the FDCA "prohibits generic drug manufacturers from independently changing their drugs' labels." *Bartlett*, 570 U.S. at 475, 477 (citing 21 C.F.R. §§ 314.94(a)(8)(iii), 314.150(b)(10) (approval for a generic drug may be withdrawn if the generic drug's label "is no longer consistent with that for [the brand-name] drug")).

Nonetheless, generic and brand-name drug manufacturers are similar in one important aspect: "Once a drug—whether generic or brand-name—is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients, or in the

specifications provided in the approved application.'" *Bartlett*, 570 U.S. at 477 (quoting 21 C.F.R. § 314.70(b)(2)(i)).

The trilogy of preemption cases the Supreme Court has decided involving drug manufacturers illustrates how the "different federal statutes and regulations" applicable to generic and brand-name drug manufacturers "lead to different pre-emption results." *See PLIVA*, 564 U.S. at 626.

First, in *Wyeth v. Levine*, a failure-to-warn lawsuit was brought against a brand-name drug manufacturer like Gilead. 555 U.S. at 558. Because it is possible for a brand-name drug manufacturer to comply with labeling requirements under both state and federal law, the Court held that the lawsuit was not preempted. *Id*. at 571–73. Specifically, the Court reasoned that the CBE regulation, 21 C.F.R. § 314.70(c)(6)(iii), permitted a brand-name drug manufacturer, like Wyeth, "to unilaterally strengthen its warning" without prior FDA approval and Wyeth had not offered any evidence "that the FDA would not have approved a change" to the drug label in question. *Id*. at 572–73.

Second, in *PLIVA, Inc. v. Mensing*, the Court held that state failure-to-warn claims brought against generic drug manufacturers were preempted by the FDCA because "it was impossible" for the defendants "to comply with both their state-law duty" to strengthen the warning on the label and "their federal-law duty to keep the label the same" as the corresponding brand-name drug labels. *PLIVA*, 564 U.S. at

610, 618–19. "[T]he CBE process was not open to the [generic manufacturers]," *id*. at 615, and, thus, "federal law would permit the [generic manufacturers] to comply with the state labeling requirements if, and only if, the FDA and the brand-name manufacturer changed the brand-name label to do so." *Id*. at 620, 624. The Court rejected the argument that preemption turned on whether the manufacturers "asked the FDA for help in changing the corresponding brand-name label." *Id*. at 619. Because the generic manufacturers could not "independently" change their drug labels "without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency," the failure-to-warn claims were preempted. *Id*. at 624.

Third, *Mutual Pharm. Co. v. Bartlett* involved a state-law "design-defect claim" brought against a generic drug manufacturer. 570 U.S. at 475. The Court held that such "state-law design-defect claims" are preempted. *See id*. at 476, 487. The Court explained that it "was not possible" for the manufacturer to "redesign" its generic drug because (a) the FDCA requires a generic drug to be chemically identical to its brand-name counterpart; and (b) the drug in question was "chemically incapable of being redesigned" due to its "simple composition," consisting of only one molecule. *Id*. at 483–84. Moreover, it was not possible to, alternatively, strengthen the drug's warning label to avoid liability because "[a]s *PLIVA* made clear, federal law prevents generic drug manufacturers from changing their labels."

Id. at 484, 486. Although the lower court had reasoned that a generic manufacturer "could escape the impossibility of complying with both its federal- and state-law duties by 'choos[ing] not to make [the generic drug] at all,'" *id*. at 488 (citation omitted), the Court rejected this "'stop-selling' rationale," holding "the prospect that a regulated actor could avoid liability under both state and federal law by simply leaving the market did not" save the plaintiff's claims from preemption under the FDCA. *Id*. at 489–90; *see also id*. at 487 n.3 ("[O]ur pre-emption cases presume that a manufacturer's ability to stop selling does not turn impossibility into possibility.").

3. Analysis: Preemption as to Evans' Claims

Liberally construed, the Court interprets the complaint to raise both pre- and post-approval design defect claims and post-approval failure to warn claims.[14] Applying the standard for impossibility preemption to these claims, the Court concludes that only Evans' design defect claims are preempted under the FDCA because it was impossible for Gilead to comply with both Hawaii tort law and the FDCA's design approval requirements.

[14]Evans does not allege that he suffered any injuries by virtue of inadequate warnings in the *original* FDA approved labeling for Truvada. In any event, the various Truvada labels provided before Evans was prescribed the drug in October 2018 are irrelevant to his failure-to-warn claims because the Truvada labeling had changed by October 2018. Dkt. No. 8 at 4; *See* FDA, *Truvada*, Drugs@FDA: FDA Approved Drugs, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=021752.

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a. Evans' Design Defect Claims are Preempted

First, to the extent Evans asserts a pre-approval design defect claim—*i.e.*, prior to Truvada receiving FDA approval, Gilead should have produced an HIV treatment or PrEP drug containing TAF, rather than TDF—this claim is preempted. Specifically, Evans alleges "Gilead abandoned its TAF (tenofovir) design in 2004" and "purposefully withheld the TAF design, which it knew was safer than TDF, to make more money." *See* Dkt. No. 8 at 7; *see id*. 6, ¶ 2 (alleging Gilead produced "a medication that it knew caused bone issues to those who took the medication, knowing it had a safer medication that would have prevented [Evans'] irreversible injuries").

The problem with Evans' theory is that it was impossible for Gilead to "independently" distribute a TAF-containing drug. *See Mensing*, 564 U.S. at 620. Doing so would have required prior FDA approval of the new drug. 21 U.S.C. § 355(a), (d); *Bartlett*, 570 U.S. at 476. Unlike the CBE process that permits "unilateral," *post-approval label* changes to be made immediately without prior FDA approval, *Wyeth*, 555 U.S. at 568; *Albrecht*, 139 S. Ct. at 1679, there is not a process under the FDCA's regime that permits a drug manufacturer to simply submit *a new drug application* and immediately begin distributing that drug until and unless the FDA rejects the application. "[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is

dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *PLIVA*, 564 U.S. at 623–24.

Other courts have reached a different conclusion based on two principal reasons, neither of which square with Supreme Court precedent.[15] First, courts have reasoned that nothing requires a brand-name manufacturer "to use the allegedly defective design in the first place." *Holley v. Gilead Scis., Inc.*, 379 F. Supp. 3d 809, 824 (N.D. Cal. 2019) (quoting *Trahan v. Sandoz, Inc.*, No. 3:13-cv-350-J-34MCR, 2015 WL 2365502, at *6 n.5 (M.D. Fla. Mar. 26, 2015)). But that theory is essentially a "never-start selling rationale" akin to the "stop-selling rationale" rejected in *Bartlett*, 570 U.S. at 488–89. *See Yates v. Ortho-Mcneil-Janssen Pharms., Inc.*, 808 F.3d 281, 300 (6th Cir. 2015) (holding that pre-approval drug design defect claims were preempted).[16] "[A] manufacturer's ability to stop selling does not turn impossibility into possibility." *See, e.g.*, *Bartlett*, 570 U.S. at 487 n.3; *id*. at 489 n.5 ("[T]he mere fact that a manufacturer may avoid liability by leaving

[15]*See Holley v. Gilead Scis., Inc.*, 379 F. Supp. 3d 809, 823–25 (N.D. Cal. 2019) (citing *In re Xarelto (Rivaroxaban) Prods. Liab. Litig.*, No. MDL 2592, 2017 WL 3188456, at *6 (E.D. La. July 21, 2017); *Young v. Bristol-Myers Squibb Co.*, No. 4:16-CV-00108-DMB-JMV, 2017 WL 706320, at *7-8 (N.D. Miss. Feb. 22, 2017); *Guidry v. Janssen Pharms., Inc.*, 206 F. Supp. 3d 1187, 1206–09 (E.D. La. 2016); *Sullivan v. Aventis, Inc.*, No. 14-CV-2939-NSR, 2015 WL 4879112, at *6 (S.D.N.Y. Aug. 13, 2015); *Estate of Cassel v. Alza Corp.*, No. 12-CV-771-WMC, 2014 WL 856023, at *2–6 (W.D. Wis. Mar. 5, 2014)).

[16]It appears the Sixth Circuit is the only Court of Appeals that has addressed whether pre-approval design-defect claims against a brand-name manufacturer are preempted. *See Holley*, 379 F. Supp. 3d at 822.

the market does not defeat a claim of impossibility."). Second, some courts have held that pre-approval design defect claims are not preempted because a drug manufacturer could have *possibly* "develop[ed] and submit[ed] for approval drugs that contained TAF rather than TDF" at an earlier date. *See Holley*, 379 F. Supp. 3d at 824 (quoting *Sullivan*, 2015 WL 4879112, at *6). *PLIVA*, however, rejected a similar rationale. *See PLIVA*, 564 U.S. at 619–21. Merely "requesting FDA assistance" or "ask[ing] the FDA for help" in complying with state law "would have satisfied [Gilead's] federal duty, [but] it would not have satisfied [Gilead]'s state tort-law duty" to provide an allegedly safer drug composition. *Id*. at 619. "The only action [Gilead] could independently take—asking for the FDA's help [by submitting a TAF-containing drug application]—is not a matter of state-law concern." *See PLIVA*, 564 U.S. at 624. In short, pre-approval design defect claims against brand-name drug manufacturers are preempted by the FDCA. *See, e.g.*, *Utts v. Bristol-Myers Squibb Co.*, 226 F. Supp. 3d 166, 185–86 (S.D.N.Y. 2016) (concluding that pre-approval design defect claim against brand-name drug manufacturer was preempted, despite plaintiffs' arguments that "defendants had a pre-approval duty to submit a differently designed drug for FDA approval" or, alternatively, "should never have sold the FDA-approved formulation of Eliquis"); *Mahnke v. Bayer Corp.*, No. 219CV07271, 2019 WL 8621437, at *5 (C.D. Cal. Dec. 10, 2019); *Brazil v. Janssen Research & Dev. LLC*, 196 F. Supp. 3d 1351, 1364 (N.D. Ga. 2016) ("This

original design theory of liability makes little sense in the face of the Supreme Court's precedents."). Accordingly, Evans' pre-approval design defect claims, if any, are preempted under the FDCA.

Second, there is no question that any post-approval design defect claim is preempted by the FDCA. "Once a drug—whether generic or brand-name—is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application.'" *Bartlett*, 570 U.S. at 477 (quoting 21 C.F.R. § 314.70(b)(2)(i)). Post-approval changes to a drug's composition are divided into three categories: "major," "moderate," and "minor" changes. *See* 21 C.F.R. § 314.70(b)–(d). Major changes require FDA "approval prior to distribution of the product made using the change," while moderate and minor changes do not. *See id*. (providing examples of changes within each category). Because changes in the "the qualitative or quantitative formulation of the drug product, including inactive ingredients" and "drug substance" are major changes, *id*. § 314.70(b)(2)(i), (iii), clearly substituting TAF for TDF as one of the active ingredients in Truvada constitutes a "major change" requiring prior FDA approval. *See, e.g.*, *Yates*, 808 F.3d at 298 (holding that post-approval design defect claim against brand-name drug manufacturers was "clearly preempted" because "federal law prohibited defendants from decreasing the dosage of estrogen post-

approval"); *Gustavsen v. Alcon Labs., Inc.*, 903 F.3d 1, 14 (1st Cir. 2018) ("[C]hanging the product bottle so as to dispense a different amount of prescription eye solution is a 'major change' under 21 C.F.R. § 314.70(b)," meaning that "plaintiffs' attempt to use state law to require such a change is preempted."); *Drescher v. Bracco Diagnostics Inc.*, 2020 WL 699878, at *8 (D. Ariz. Jan. 31, 2020) (post-approval design-defect claim against brand-name manufacturer preempted because the design change advocated for "would constitute a major change under the regulations" requiring "prior FDA approval"); *Paulsen v. Abbott Labs.*, 368 F. Supp. 3d 1152, 1173 (N.D. Ill. 2019) ("[A]ny claims by Plaintiff that TAP should have changed the formulation of Lupron is preempted by FDA regulations that prohibit a change in the formulation of a drug once it has been approved."); *Batoh v. McNeil-PPC, Inc.*, 167 F. Supp. 3d 296, 322 (D. Conn. 2016) (post-approval design defect claim preempted because "[i]f Defendants had unilaterally changed the active ingredient of Motrin from ibuprofen to dexibuprofen to satisfy their state law duty, they would have violated federal law"). Accordingly, insofar as Evans asserts that Gilead should have changed the formulation of Truvada after it was approved by the FDA, this claim is preempted by the FDCA.

In sum, Evans' design defect claims are dismissed with prejudice as preempted by the FDCA. Because any amendment to the complaint will not change

the law, leave to amend these claims would be a "futile exercise" and is, therefore, denied. *Parents for Privacy v. Barr*, 949 F.3d 1210, 1239 (9th Cir. 2020).

b. Evans' Failure-to-Warn Claims are Not Preempted

As noted, Evans only asserts post-approval failure-to-warn claims. *See supra* n.14. Gilead contends that Evans "has not alleged any 'newly acquired information'" that would permit Gilead to utilize the CBE process to make a post-approval change to its Truvada labeling and, thus, Evans "cannot state a non-preempted claim based on a purported post-approval failure to warn." *See* Dkt. No. 20-1 at 30; *supra* Section I.B.2. Gilead misapprehends both its burden in establishing its preemption defense and the procedural posture of this case. *Wyeth*, 555 U.S. at 569.

First, Evans is not required to plead the existence of "newly acquired information."[17] "FDCA preemption, like all federal preemption, is an affirmative defense." *Durnford v. MusclePharm Corp.*, 907 F.3d 595, 603 (9th Cir. 2018)

[17]The FDA regulations define "newly acquired information" as "data, analyses, or other information not previously submitted to the Agency, which may include (but is not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events, or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to [the] FDA." 21 C.F.R. § 314.3(b); *see Wyeth*, 555 U.S. at 569 ("The rule accounts for the fact that risk information accumulates over time and that the same data may take on a different meaning in light of subsequent developments"). Given that the "process of submitting an NDA is both onerous and lengthy," typically "span[ning] thousands of pages and is based on clinical trials conducted over several years," *Bartlett*, 570 U.S. at 476 (citation omitted), requiring a plaintiff to allege "new clinical studies, reports of adverse events, or new analyses" would give new meaning to the phrase "short and plain" under Rule 8(a)(2).

(quoting *Lusnak*, 883 F.3d at 1194 n.6). "Only when the plaintiff pleads itself out of court—that is, admits all the ingredients of an impenetrable defense—may a complaint that otherwise states a claim be dismissed under Rule 12(b)(6)." *Id.* (quoting *Xechem, Inc. v. Bristol-Myers Squibb Co.*, 372 F.3d 899, 901 (7th Cir. 2004)); *Lusnak*, 883 F.3d at 1194 n.6 ("Ordinarily, affirmative defenses such as preemption may not be raised on a motion to dismiss except when the defense raises no disputed issues of fact."). As such, whether "newly acquired information" existed prior to when Evans was prescribed Truvada, is an issue for post-discovery motion practice. *See Wyeth*, 555 U.S. at 569, 571.

Second, even if there was little or no "newly acquired information" relevant to Evans' claims, that did not make it *impossible* for Gilead to change its Truvada label. The FDA's CBE regulation permits a brand-name drug manufacturer, like Gilead, to file a supplemental application and then immediately "change a label to 'reflect newly acquired information' if the changes 'add or strengthen a . . . warning' for which there is 'evidence of a causal association,' without prior approval from the FDA." *See, e.g.*, *Albrecht*, 139 S. Ct. at 1679 (quoting 21 C.F.R. § 314.70(c)(6)(iii)(A)); *Wyeth*, 555 U.S. at 568 ("[I]t may make the labeling change upon filing [a] supplemental application with the FDA; it need not wait for FDA approval."). Thus, Gilead could have filed a supplemental application and immediately changed its Truvada label. *See Wyeth*, 555 U.S. at 571 ("Wyeth had a

duty to provide a warning that adequately described that risk, and the CBE regulation permitted it to provide such a warning before receiving the FDA's approval."). As the Supreme Court recently emphasized:

> Of course, the FDA reviews CBE submissions and can reject label changes even after the manufacturer has made them. *See* §§ 314.70(c)(6), (7). . . . But in the interim, the CBE regulation permits changes, so a drug manufacturer will not ordinarily be able to show that there is an actual conflict between state and federal law such that it was impossible to comply with both.

Albrecht, 139 S. Ct. at 1679; *Wyeth*, 555 U.S. at 571 ("[A]bsent clear evidence that the FDA would not have approved a change to Phenergan's label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements."); *PLIVA*, 564 U.S. at 624 n.8. As explained, state law failure-to-warn claims are only preempted by the FDCA and related labeling regulations when the drug manufacturer produces "'clear evidence' that the FDA would not have approved the warning [change] that state law requires." *Albrecht*, 139 S. Ct. at 1676 (quoting *Wyeth*, 555 U.S. at 571). In 2019, the Supreme Court held that "'clear evidence' is evidence that shows the court that the drug manufacturer fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning." *Id*. at 1672; *id*. at 1678.

Gilead has not offered such evidence. Gilead has not shown that it filed a supplemental application, changed its Truvada labeling to include a warning for the

injuries Evans allegedly suffered, and that the FDA later rejected that change. The notion that perhaps there was not sufficient "newly acquired information" or "evidence of a causal association" between Truvada and the risk of injuries alleged here, 21 C.F.R. § 314.70(c)(6)(iii)(A), are merely two of any number of reasons for the FDA to reject the label changes after Gilead had made them. But federal law did not preclude Gilead from making a label change in the interim.

Accordingly, Evans' failure-to-warn claims are not preempted by the FDCA and its labeling regulations.

II. Failure-to-Warn Claims: Merits

Beyond preemption, Gilead contends that Evans' failure-to-warn claims fail for two reasons: "(1) the Truvada® labeling contained the warnings that [Evans] incorrectly alleges were lacking; and (2) [Evans] fails to adequately allege the causation required to sustain such a claim." Dkt. No. 20-1 at 11. Only the latter is true.

First, the Truvada labeling did not contain the specific warnings relevant to this case. A manufacturer has a duty to "give appropriate warning of any known dangers which the user of its product would not ordinarily discover." *Acoba*, 986 P.2d at 305 (quoting *Ontai*, 659 P.2d at 743); *Tabieros*, 944 P.2d at 1297–98. "[I]n a strict products liability action, the issue of whether the seller knew or reasonably should have known of the dangers inherent in his or her product . . . has absolutely

no bearing on the elements of a strict products liability claim." *Tabieros*, 944 P.2d at 1298 n.11 (quoting *Johnson v. Raybestos-Manhattan, Inc.*, 740 P.2d 548, 549 (Haw. 1987)). "When a product warning has been provided by a manufacturer, the adequacy of that warning is generally a question of fact for the jury." *Acoba*, 986 P.2d at 302 (collecting cases). "In rare instances, however, warnings may be found adequate as a matter of law." *Id*. (citing *Temple v. Velcro USA, Inc.*, 196 Cal. Rptr. 531, 533 (Cal. Ct. App. 1983)). For example, a warning may be deemed adequate as a matter of law where it is "very clear, understandable and completely unambiguous" and "forcefully [brings] home the intended message." *Temple*, 196 Cal. Rptr. at 533.

Here, Evans alleges that Truvada's prescriber and patient labeling did not disclose that: (a) the drug "could cause damage to the kidneys and to the bones of those who ingest it," including "the problems that [Evans] is now suffering" (*i.e.*, diffuse arthralgia); and (b) doctors should "monitor all TDF patients, on a frequent, specific schedule, for the adverse effects of TDF-associated bone and kidney toxicity." *See* Dkt. No. 8 at 2, 6–7.

Although the Truvada labeling provided at the relevant time warned of "[b]one problems," including "bone pain, or softening or thinning of bones, which may lead to fractures"; "[d]ecreases in bone mineral density (BMD)"; and "Bone Loss and Mineralization Defects," Dkt. No. 20-2 at 1, 7–8, 12, 37, the particular

injury at issue here is "diffuse arthralgia." Dkt. No. 8 at 2, 7. In that regard, the most the label says is that "in association with TDF use . . . [a]rthralgia and muscle pain or weakness have also been reported in cases of proximal renal tubulopathy." *Id*. at 8. The label mentions "arthralgia" but only as a risk in patients with a specific condition—"proximal renal tubulopathy"—and that specific and important fact is conspicuously omitted in Gilead's brief and replaced with an ellipsis. Dkt. No. 20-1 at 7. The complaint does not indicate Evans has "proximal renal tubulopathy." As a result, the Court cannot say, as a matter of law, that the label warns patients like Evans of the risk of arthralgia in terms that are "completely unambiguous" and "forcefully [bring] home the intended message." *Temple*, 196 Cal. Rptr. at 533.

The warning for doctors to monitor TDF patients' "bone mineral density" suffers from the same defect. *See* Dkt. No. 20-2 at 1 ("Monitor for evidence of tenofovir toxicity."); *id*. at 33 ("Consider bone monitoring in patients and uninfected individuals *who have a history of pathologic bone fracture or at risk for osteopenia*" (emphasis added)). The label recommends monitoring patients with a history of particular conditions, none of which are known to be germane to Evans. Therefore, a reasonable jury could conclude that these warnings were inadequate. As such, the adequacy of the label in this case is a question for the jury.

Gilead, however, also argues that Evans has failed to allege that any failure to warn was the proximate cause of Evans' injuries. Specifically, Gilead contends that

to do so Evans "must allege that his doctor would have acted differently (*e.g.*, not prescribed Truvada®) had Gilead provided supposedly adequate warnings." Dkt. No. 20-1 at 14. Although Hawaii courts have not directly addressed this specific issue, the Court predicts that the Hawaii Supreme Court would adopt a similar rule.[18]

"[I]n order for a manufacturer to be liable for failing to provide an appropriate warning, it must not only be subject to a legal duty to warn, but the breach of that duty (*i.e.*, the failure to give an adequate warning) must have been the legal cause of the plaintiff's injuries." *Tabieros*, 944 P.2d at 1313. "Proof of defect [*i.e.*, manufacture, design, or failure to warn] *and causation* may be provided by expert testimony or *by circumstantial evidence*." *Acoba*, 986 P.2d at 304 (emphasis added); *see Tabieros*, 944 P.2d at 1296–97. Hawaii adheres to the "learned intermediary" rule in the "the prescription drug arena." *See Craft v. Peebles*, 893 P.2d 138, 155 (Haw. 1995). "The learned intermediary rule . . . assumes that it is reasonable for a manufacturer to rely on the prescribing physician to forward to the patient, who is the ultimate user of the drug products, any warnings regarding their possible side effects." *Id*. (citation omitted). As such, the "the adequacy of [a manufacturer's] warning is measured by the effect on the *physician*, . . . to whom it owed a duty to

[18]*See PSM Holding Corp. v. Nat'l Farm Fin. Corp.*, 884 F.3d 812, 820 (9th Cir. 2018) ("[A] federal court must predict how the highest state court would decide the issue using intermediate appellate court decisions, decisions from other jurisdictions, statutes, treatises, and restatements as guidance.").

warn, and not by its effects on [the patient]." *Id*. at 156 (citation omitted; emphasis in original). It follows then, as other jurisdictions have concluded, that "[w]hen a plaintiff brings an insufficient warning claim against a drug company, the learned intermediary doctrine requires a showing that the prescribing physician, not the patient, would have taken 'a different course of action' if better warnings had been issued." *See, e.g.*, *Luttrell v. Novartis Pharms. Corp.*, 555 F. App'x 710, 710 (9th Cir. 2014) (citations omitted; applying Washington law); *Motus v. Pfizer, Inc.*, 358 F.3d 659, 661 (9th Cir. 2002) (applying California law); *Tapia v. Davol, Inc.*, 116 F. Supp. 3d 1149, 1158 (S.D. Cal. 2015) (applying California law); *see also Holley*, 379 F. Supp. 3d at 830 ("[T]he relevant question is whether the plaintiff's physician would have 'prescribed the drug in the same manner.'" (quoting *Alston v. Caraco Pharm., Inc.*, 670 F. Supp. 2d 279, 285 (S.D.N.Y. 2009)).

Here, Evans has not adequately alleged causation because he has not asserted that stronger warnings would have led his physician to either prescribe a medication other than Truvada, prescribe the drug in a different manner, or prescribe nothing at all. Evans merely alleges that Gilead "[i]ntentionally omitting the warnings from their labeling caused [Evans] to be diagnosed with Diffuse Arthralgia, secondary to use of Truvada," and that Gilead's "negligence caused [Evans] the harm he now suffers." Dkt. No. 8 at 2, 8; *see also id*. at 7 ("The action or inaction has caused [Evans] with Diffuse Arthralgia."). These "labels and conclusions . . . will not

do." *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 555). Evans must allege that had the Truvada label contained a stronger warning of the risk of diffuse arthralgia, this would have altered his prescribing physician's "course of action" in some meaningful way. Because Evans has not done so, his failure-to-warn claim is dismissed, albeit with leave to amend.

III. Fraud

Evans alleges that he "is suing for," among other things, "Fraud." Dkt. No. 8 at 8. Gilead contends this claim must be dismissed because it does not meet the pleading requirements under Federal Rule of Civil Procedure 9(b) for claims sounding in fraud. Dkt. No. 20-1 at 16. The Court agrees. Evans is far from satisfying the "particularity" pleading requirements of Rule 9(b). *See Odom v. Microsoft Corp.*, 486 F.3d 541, 553 (9th Cir. 2007) (*en banc*).

To establish a fraud claim, a plaintiff must allege the following elements: "(1) false representations were made by [the defendant], (2) with knowledge of their falsity (or without knowledge of their truth or falsity), (3) in contemplation of plaintiff's reliance upon these false representations, and (4) plaintiff did rely upon them." *Shoppe v. Gucci Am.*, 14 P.3d 1049, 1067 (Haw. 2000) (quoting *TSA Int'l Ltd. v. Shimizu Corp.*, 990 P.2d 713, 725 (Haw. 1999)). Rule 9(b), in turn, states that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed.R.Civ.P.9(b); *see Vess v. Ciba-*

Geigy Corp. USA, 317 F.3d 1097, 1103 (9th Cir. 2003) ("Rule 9(b)'s particularity requirement applies to state-law causes of action."). To satisfy Rule 9(b), "the pleading must identify the who, what, when, where, and how of the misconduct charged, as well as what is false or misleading about the purportedly fraudulent statement, and why it is false." *Depot, Inc. v. Caring for Montanans, Inc.*, 915 F.3d 643, 668 (9th Cir. 2019) (citations and internal quotation marks omitted). In other words, Evans "must state the time, place, and specific content of the false representations as well as the identities of the parties to the misrepresentation." *Odom*, 486 F.3d at 553 (citation omitted).

The missing pieces here are *who* stated *what* to *whom* and *when* and *where* was the statement made, as well as some allegation as to what makes the statement(s) false or misleading. Nor is there any allegation in the complaint that Evans and his physician(s) relied on any such misrepresentation. *See Craft*, 893 P.2d at 156. Rather, Evans has simply stated in conclusory terms that Gilead was "defrauding those taking this medication, including [Evans], for their own financial benefit." Dkt. No. 8 at 5. This presumably relates to Evans' contention that Gilead "purposefully withheld the TAF design," Dkt. No. 3, 7, but that decision, even accepted as true, does not constitute an actionable claim for fraud.

Accordingly, Evans' fraud claim is dismissed with leave to amend.

IV. Breach of Express and Implied Warranty

That leaves Evans' claim for "Breach of Express and Implied Warranty." Dkt. No. 8 at 8.[19] These claims are also dismissed as insufficiently pled because the complaint merely "tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 557).

Under Hawaii law, three categories of warranties are prescribed by statute: express; implied warranty of fitness for a particular purpose; and implied warranty of merchantability. *See* Haw. Rev. Stat. §§ 490:2-313, -314, -315.

> Express warranties are created as follows:
>
> (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
>
> (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.
>
> (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

See Haw. Rev. Stat. § 490:2-313(1). "It is not necessary to the creation of an express warranty that the seller use formal words such as 'warrant' or 'guarantee' or that he have a specific intention to make a warranty, but an affirmation merely of the value

[19]To the extent Evans asserts a claim for "Negligence and Gross Negligence – Design Defect and Failure to Warn," Dkt. No. 8 at 8, such claims are necessarily dismissed because, as explained above, Evans' design defect claims are preempted by the FDCA, and he has not adequately alleged causation as to his failure-to-warn claim.

of the goods or a statement purporting to be merely the seller's opinion or commendation of the goods does not create a warranty." *Id*. § 490:2-313(2). Thus, to state a breach of express warranty claim, Evans must allege that: "(1) [Gilead] made an affirmation of fact or promise regarding the product, (2) that statement became part of the basis of the bargain, and (3) the product failed to perform according to the statement." *Nielsen v. Am. Honda Motor Co.*, 989 P.2d 264, 274–75 (Haw. Ct. App. 1999); *Torres v. Northwest Eng'g Co.*, 949 P.2d 1004, 1015 (Haw. Ct. App. 1997).

Here, the defect in Evans' express warranty claim is that he has failed to allege that Gilead made a specific "affirmation or promise" regarding Truvada or that Gilead provided a "description of [Truvada]" that failed to live up to its billing. Therefore, Evans' express warranty claim is dismissed with leave to amend.

Implied warranties come in two forms, but Evans has not specified which theory he is pursuing. "The implied warranty of merchantability is perhaps the broadest warranty in the Uniform Commercial Code." *Ontai*, 659 P.2d at 744. "This warranty is implied by operation of law into every sale of goods by a merchant seller." *Id*. "Merchantability, as provided in Hawaii's statute, means, *inter alia*, that the goods 'are fit for the ordinary purpose for which such goods are used." *Id*. (quoting Haw. Rev. Stat. § 490:2-314(2)(c)). Thus, to state a claim for breach of the implied warranty of merchantability, Evans must allege "(1) the seller is a merchant

of such goods, and (2) the product was defective or unfit for the ordinary purpose for which it is used."[20] *Nielsen*, 989 P.2d at 274; *see also Larsen v. Pacesetter Sys., Inc.*, 837 P.2d 1273, 1284–85 (Haw. 1992) ("[T]o bring an action in implied warranty for personal injury[,] a plaintiff is required to show product unmerchantability sufficient to avoid summary judgment on the issue of defectiveness in a tort strict products liability suit.").

By contrast, "the implied warranty of fitness for a particular purpose is narrower and more specific." *Ontai*, 659 P.2d at 744. When the seller "has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is . . . an implied warranty that the goods shall be fit for such purpose." Haw. Rev. Stat. § 490:2-315. "[T]he buyer need not bring home to the seller actual knowledge of the particular purpose for which the goods are intended or of his reliance on the seller's skill and judgment, if the circumstances are such that the seller has reason to realize the purpose intended or that the reliance exists." *Ontai*, 659 P.2d at 744 (quoting Haw. Rev. Stat. § 490:2-315 cmt. 1). Therefore, to adequately allege a claim for breach of the implied warranty of fitness, Evans must allege that: "(1) [Evans] desired a product for a particular purpose, (2) [Gilead] had reason to know

[20]The Court notes that any defect based on Truvada's drug composition is necessarily preempted by the FDCA. *See supra* Section I.B.3.a.

about this purpose, and (3) the product sold to [Evans] failed to meet that purpose." *Nielsen*, 989 P.2d at 274.

Because Evans does not allege which implied warranty claim(s) he is pursuing (*i.e.*, merchantability and/or fitness), Gilead (and the Court) are left to guess. That is not "fair notice of what the . . . claim is and the grounds upon which it rests." *Twombly*, 550 U.S. at 555 (ellipsis in original) (quoting *Conley*, 355 U.S. at 47). Moreover, Evans does not contend Truvada failed to perform as an HIV treatment or PrEP medication for HIV. For these reasons, Evans' "implied warranty" claim is dismissed. Evans, however, is granted leave to amend.[21]

CONCLUSION

For the reasons set forth herein, Defendant's Motion to Dismiss the First Amended Complaint, Dkt. No. 20, is GRANTED, and the First Amended Complaint is DISMISSED.

[21]To assist Evans, the Court will mail Evans a copy of a form complaint for use in a civil *pro se* proceeding, such as this one. Should Evans choose to use the form, he should answer **all of the questions** clearly and concisely. Evans should set out each claim under a separate label or heading. Under each claim, Evans must write short, plain statements telling the Court the following: (1) the specific basis for this Court's jurisdiction; (2) the legal right(s) he believes were violated; (3) the name of the defendant(s) who violated those right(s); (4) exactly what each defendant did or failed to do and the underlying facts that provide support; (5) *how the action or inaction of a defendant is connected to the violation* of Evans' right(s); (6) what specific injury he suffered because of a defendant's conduct; and (7) what relief he seeks. Should Evans choose to file an amended complaint, he may not incorporate any part of his present complaint, Dkt. No. 1, in the amended complaint. Rather, all allegations must be re-typed or re-written in their entirety. *See Lacey v. Maricopa Cty.*, 693 F.3d 896, 928 (9th Cir. 2012) (*en banc*); LR 10.4.

Plaintiff may have until **September 21, 2020** to file an amended complaint, to the extent allowed herein and consistent with a litigant's ethical obligations under Fed.R.Civ.P. 11(b). **The Court cautions Evans that failure to file an amended complaint by September 21, 2020, may result in the automatic dismissal of this action.**

The Clerk is directed to mail Evans a copy of form "Pro Se 1" "Complaint for a Civil Case."

IT IS SO ORDERED.

DATED: August 31, 2020 at Honolulu, Hawai'i.

Derrick K. Watson
United States District Judge